No. 11690

IN THE

United States Circuit Court of Appeals

FOR THE NINTH CIRCUIT

PASADENA RESEARCH LABORATORIES, INC., a corporation, and RUSSELL R. BAVOUSET,

Appellants,

vs.

UNITED STATES OF AMERICA,

Appellee.

APPELLEE'S BRIEF.

JAMES M. CARTER,
United States Attorney,

ERNEST A. TOLIN,
Chief Assistant U. S. Attorney,

NORMAN W. NEUKOM,
Assistant U. S. Attorney,
Chief of Criminal Division,
United States Postoffice and
Courthouse Building, Los Angeles 12,
Attorneys for Appellee.

ARTHUR A. DICKERMAN,
Of Counsel—Attorney, Federal Security Agency.

Parker & Company, Law Printers, Los Angeles. Phone TR. 5206.

TOPICAL INDEX

TABLE OF AUTHORITIES CITED

STATUTES

TEXTBOOKS

No. 11690

IN THE

United States Circuit Court of Appeals

FOR THE NINTH CIRCUIT

PASADENA RESEARCH LABORATORIES, INC., a corporation, and RUSSELL R. BAVOUSET,

Appellants,

vs.

UNITED STATES OF AMERICA,

Appellee.

APPELLEE'S BRIEF.

I.

STATEMENT OF JURISDICTION.

Pursuant to Title 21, U. S. C., Section 331(a) and 333(a), as well as Title 28, U. S. C., Section 41(2), the District Court had jurisdiction to try the defendants.

Under Title 28, U. S. C., Sections 225(a) and (d), this court has authority to review the judgment of the District Court.

II.

STATEMENT OF THE FACTS.

The Information filed in this case charges the defendants in seven counts with violations of the Federal Food, Drug and Cosmetic Act, resulting from the interstate shipment of drugs that were adulterated and misbranded.

After trial without a jury [R. 17], the District Court found both defendants, Appellants here, guilty as to Counts I, II, III, IV and VII, but not guilty as to Counts V and VI.

While defendants were convicted on five counts, sentence was imposed as for three offenses [R. 20]. Counts I and II involve the same product, the same shipment and the same evidence, the only difference being that in Count I, the product is charged with being adulterated, while in Count II, the product is charged with being misbranded. A parallel situation exists between Counts III and IV. Count VII stands alone.

A. Sterile Indoform.

[Counts I and II, Exhibits 3, 4 and 5.]

The Information charges, in Count I, that when this drug "Sterile Indoform" was introduced into interstate commerce, it was adulterated within the meaning of Title 21, U. S. C., Section 351(c) since its strength differed from what it purported and was represented to possess [R. 2-3]. The label declares the presence of *three* International Units of *posterior pituitary* and *one grain* of *thyroid substance;* whereas, the Government contended the drug contained a lesser amount of posterior pituitary and no thyroid substance. We submit the evidence fully supported this contention.

Count II charges that the "Indoform" was misbranded within the meaning of Title 21, U. S. C., Section 352(a), in that the label statements with respect to the presence of posterior pituitary and thyroid substance are false and misleading [R. 4-5].

By stipulation [R. 14], it was admitted that defendants shipped a number of vials containing the product "Indoform" in interstate commerce on or about September 17, 1945, from Pasadena, California, to Dr. Joseph C. Bunten, Cheyenne, Wyoming, labeled as described in Counts I and II. It was also stipulated that on or about January 24, 1946, Food and Drug Inspector Davidson collected a sample of this shipment from Dr. Bunten, consisting of one vial and contents. After sealing this sample with an official seal, properly identified, Inspector Davidson forwarded the sample by United States Mail to the Pharmacology Division, Food and Drug Administration, Washington, D. C.

Before outlining the Government's evidence as to the adulterated and misbranded condition of this "Indoform," it is highly pertinent to note that the appellant Russell R. Bavouset admitted the Government's contention with respect to *posterior pituitary*—namely, that this shipment of "Indoform" contained such small quantities of posterior pituitary as to be immeasurable [R. 143-4]. This admission was based upon an independent test conducted by the Cooper Laboratories at defendants' behest, after the shipment was made.

The Government's affirmative evidence with respect to the deficiencies in "Indoform," as to posterior pituitary, stems from the testimony of Arnold E. Mason. Mr. Mason had been employed with the Food and Drug Administration as a pharmacologist and analyst, though at the time of trial he testified he was then employed as a pharmacologist with Crystal (Bristol) Laboratories, Syracuse, New York [R. 57].

On February 18, 1946, while still with the Food and Drug Administration, Washington, D. C., Mr. Mason

analyzed the sample of "Indoform" which Inspector Davidson had collected, to determine the presence of posterior pituitary. His method of analysis was that prescribed by the United States Pharmacopoeia [R. 80]. In his testimony, Mr. Mason gave a detailed description of the method he used [R. 60-73, 80-84, 215-225].

Mr. Mason found that the "Indoform" he examined contained practically no posterior pituitary; if it contained any at all, the amount was immeasurable [R. 59, 74].

Mr. Mason also testified that posterior pituitary is very stable except at excessively high temperatures; it would break down if it were boiled at 212° Fahrenheit for five or six hours [R. 73-74]. Otherwise, it would remain stable and continue its effectiveness for many months, and even years [R. 74].

Mr. Mason expressed the opinion that on the date defendants shipped the product "Indoform" interstate, September 17, 1945—five months before his analysis, it could *not* have contained three units of posterior pituitary per cubic centimeter; and stated that on that date, if the product contained any posterior pituitary at all, it was an immeasurable quantity [R. 75-76].

The label of the product "Indoform" contains no cautionary statement prescribing a particular mode of storage [Govt's Ex. 4, R. 63].

Mr. Mason further testified that when he received the sample of "Indoform" [Govt's Ex. 3], the vial was full and the rubber stopper or cork was protected with a celluloid seal *around* it; and that it appeared as if it had never been opened [R. 215, 79-80].

Appellants' witness, Dr. Icke, who is employed as director of research at the Pasadena Research Laboratories,

testified that one of the ingredients of "Indoform," suprarenal cortex extract, contains adrenalin which would interfere with the test for posterior pituitary so that the latter ingredient would not be as active as it would if the adrenalin were not present [R. 179-181].

In rebuttal, Mr. Mason testified that the cortex might contain very small amounts of adrenalin [R. 216]. Such minute amounts would be destroyed in the course of the test he made [R. 225]. Mr. Mason stated the test he conducted is just as accurate as if there were no suprarenal cortex present [R. 217]. He stated he has conducted many similar tests upon other preparations of the same nature, which included suprarenal cortex, and was able to establish the presence of the amount of posterior pituitary claimed [R. 217].

A significant fact with respect to the test conducted by Mr. Mason is that he used the "Indoform" in full strength [R. 73], whereas the standard solution against which he tested the "Indoform" was diluted fifty times [R. 72]. Also, the standard solution was made from a preparation containing *two* units of posterior pituitary per cc., whereas the "Indoform" here involved was labeled to contain *three* units per cc. [R. 72]. Thus, if the "Indoform" contained the declared amount of posterior pituitary, it would have been over fifty times as strong as the standard solution [R. 73]. Nevertheless, the "Indoform" did not give a reaction in the test showing even a measurable amount of posterior pituitary [R. 73, 83-4].

Mr. Mason did not add anything to the vial of "Indoform" or tamper with its contents [R. 77]. After conducting his tests, he sent the vial to San Francisco for further analysis [R. 77].

Mr. Buell, a chemist of the Food and Drug Administration at San Francisco, received the vial of "Indoform" transmitted from Mr. Mason. On March 27, 1946, he analyzed this product for its *thyroid* content, as indicated by the presence of organically combined iodine [R. 87]. The label of the product declares the presence of "Thyroid Substance 1 gr." [R. 63]. Mr. Buell found no organically combined iodine at all [R. 89].

Mr. Buell testified that the label statement "Thyroid Substance 1 gr." means that the product contains one grain of the active constituent of the thyroid as organically combined iodine [R. 89]. Buell stated that thyroid is extremely stable [R. 89-90]. When defendants shipped the "Indoform" interstate it did not, in Mr. Buell's opinion, contain thyroid substance present as organically combined iodine [R. 90].

The United States Pharmacopoeia defines and describes "thyroid" as follows [R. 136-7]:

> "Thyroid is the cleaned, dried and powdered thyroid gland previously deprived of connective tissue and fat.
>
> * * * * * * * *
>
> "It is obtained from domesticated animals that are used for food by man. *Thyroid contains not less than 0.17 per cent and not more than 0.23 per cent of iodine in thyroid combination,* and must be free from iodine in inorganic or any form of combination other than peculiar to the thyroid gland."

Appellants admitted that "Indoform" contains no organically combined iodine [R. 110], but contended that the product does not purport to contain such iodine by

reason of the disclaimer on the label [R. 111]. The label disclaimer reads [R. 63]:

> "This preparation does not contain any known therapeutically useful constituent."

Appellants assert that the product contains a water extract of desiccated thyroid not including its iodine content [R. 111]. Appellant Bavouset, manager of the Research Laboratories, stated he did not know the type of material that is designated by the term "thyroid substance" as used on the label [R. 111].

Despite the disclaimer on the label, Mr. Bavouset admitted that posterior pituitary and whole ovarian, which are other ingredients of "Indoform" [R. 63], do have therapeutic value [R. 135].

B. Sterile Solution Pluri-B.

[Counts III and IV, Exhibits 6 and 7.]

The Information charges in Count III that when this product, "Pluri-B," was introduced into interstate commerce it was adulterated within the meaning of Title 21, U. S. C., Section 351(c), since its strength differed from what it purported and was represented to possess [R. 5-6]. The label declares the presence of *50 milligrams* of *thiamine hydrochloride in each cubic centimeter,* whereas the Government contended the drug contained a lesser amount of thiamine hydrochloride.

The Government's proof indicated that the product contained but 33 milligrams rather than 50 milligrams.

Count IV charges that the "Pluri-B" was misbranded within the meaning of Title 21, U. S. C., Section 352(a), in that the label statements with respect to the presence of thiamine hydrochloride are false and misleading [R. 7-8].

By stipulation [R. 15], it was admitted that appellants shipped a number of vials containing the product "Pluri-B" in interstate commerce on or about July 16, 1945, from Pasadena, California, to Dr. Clement Swain, Reno, Nevada, labeled as described in Counts III and IV. It was also stipulated that on or about August 30, 1945, Food and Drug Inspector Griebling obtained a sample of this shipment from Dr. Swain, consisting of two vials and contents. After sealing this sample with an official seal, properly identified, Inspector Griebling forwarded the sample by United States Mail to the Vitamin Division, Food and Drug Administration, Washington, D. C.

Dr. Tolle, Assistant Chief of the Vitamin Division of the Food and Drug Administration, among his other duties, is charged with the receipt and distribution of samples for analysis [R. 212]. When he received the vial identified as Government's Exhibit 6 *"Pluri-B,"* he observed that the vial appeared to be full and appeared not to have been tampered with [R. 212]. Dr. Tolle stated it is the practice of the Administration to have its inspectors note on their collection reports that a sample has been opened, if it has been; in such event, Dr. Tolle would not have had the sample analyzed in his laboratory [R. 213].

Mr. Capps, a chemist in the Vitamin Division, testified that on September 24, 1945, he examined the vial of "Pluri-B" identified as Exhibit 6 [R. 99]. While the label declares the presence of 50 milligrams of thiamine hydrochloride per cc., his examination showed that the drug contained 33 milligrams of thiamine hydrochloride per cc. [R. 99-100]. In making this examination, he followed the thiocrome procedure for thiamine described in the United States Pharmacopoeia [R. 98-99]. The record shows the details of this procedure [R. 101-106].

Chemist Capps stated that in a properly made solution, thiamine hydrochloride is stable except when exposed to extremely high temperatures [R. 100]. Appellant Bavouset testified that it was in a proper acid base and would substantially retain its potency for a year [R. 131, 149, 151]. Bavouset further stated that their products are all bottled and sealed in accordance with the most improved methods, designed (1) to prevent impurities from getting in; (2) to protect the contents from light; and (3) to keep the contents in a reasonably good state of preservation [R. 131-132].

In chemist Capp's opinion, the vial of "Pluri-B" which he examined did not contain more than 33 milligrams of thiamine hydrochloride per cc. when it was shipped interstate on July 16, 1945, less than two months before he analyzed it [R. 100-101].

Mr. Bavouset admitted that at the time this drug was shipped his laboratory did not have the equipment to make the thiocrome determination for thiamine [R. 144].

C. Sterile Solution Pluri-B.

[Count VII, Exhibits 1 and 2.]

The Information charges in Count VII that when this product, another type of "Pluri-B" was introduced into interstate commerce it was adulterated within the meaning of Title 21, U. S. C., Section 351(c), since its purity and quality fell below that which it purported and was represented to possess [R. 10-12]. Thus the drug was represented as suitable for intramuscular and intravenous use, a use which requires the product to be free from undissolved material, whereas the Government contended and proved that this drug contained *undissolved material.*

By stipulation [R. 16], it was admitted that appellants shipped a number of vials containing the product "Pluri-B" in interstate commerce on or about June 18, 1946, from Pasadena, California, to Dr. P. M. Ryerson, Phoenix, Arizona, labeled as described in Count VII. It was also stipulated that on or about July 12, 1946, Food and Drug Inspector Kerr collected a sample of this shipment from Dr. Ryerson, consisting of six vials and contents. After sealing this sample with official seals properly identified, Inspector Kerr forwarded it by Railway Express to the Pharmacology Division, Food and Drug Administration, Washington, D. C.

Dr. Wiley, Chief of the Chemical Section, Medical Division, Food and Drug Administration, Washington, D. C., with specialized training in biochemistry, testified that he received this sample "Pluri-B" on July 23, 1946, and

examined it on August 1, 1946 [R. 33, 38]. Dr. Wiley stated that all of the vials in the sample were sealed, capped and full when he received same [R. 226].

On examination, Dr. Wiley found that all six vials in the sample were very badly contaminated with undissolved material; that is, they contained a considerable quantity of material which was not in solution and was visible with the naked eye [R. 34].

The amount of undissolved material in the vials was the same on the date of Dr. Wiley's testimony, June 17, 1947, as on the day he first examined the sample, August 1, 1946 [R. 37-38]. In his opinion, the undissolved material was present on June 18, 1946, the date when appellants shipped this "Pluri-B" interstate [R. 42].

The label of the product contains no statement as to the conditions under which it should be stored [R. 43].

Only such an improbable factor as transmitting the sample to Washington in a refrigerator car might have hastened the crystallization, if it had not already taken place [R. 42].

Dr. Wiley testified that the presence of the noted undissolved materials in the vials was caused by a supersaturated solution of riboflavin [R. 44]. He stated that in the product there was about twenty times as much riboflavin as may ordinarily be dissolved in a water solution [R. 46]. Riboflavin is stable and would remain in solution if the amount dissolved is below the saturation point [R. 44].

Mr. Bavouset testified that the undissolved material present was a precipitate of riboflavin, and that very often in such a case, putting the product in warm water would cause the riboflavin to go back into solution [R. 145]. He also stated that in his opinion nothing had been added to the vials in Exhibit 1, 'Pluri-B," other than what he had put into them [R. 146].

Dr. Icke, appellants' witness, testified that the undissolved particles in Government's Exhibit 1, should dissolve if the vial were put in lukewarm water with a temperature of 110°—120° Fahrenheit [R. 190].

In rebuttal, Dr. Wiley testified that in the course of his examination of this sample, he had placed the vials in warm water of about 150° Fahrenheit for 10-15 minutes; at the end of that time the undissolved material was still present [R. 226-227].

Dr. Clinton H. Thienes, medical doctor and pharmacologist, testified to the dangers inherent in a "sterile solution" which is intended for intravenous or intramuscular injection and which contains undissolved particles; such a product may cause blockage of circulation, shock, pain and infection [R. 49-50]. Dr. Thienes stated that it is the consensus of practitioners that such solutions must be free from undissolved particles [R. 50]. This is the view also expressed in the United States Pharmacopoeia [R. 50]. In the opinion of Dr. Thienes, the contents of the vials in Government's Exhibit 1, do not meet the standards for a sterile solution intended for intramuscular and intravenous use [R. 51].

III.
STATUTORY PROVISIONS INVOLVED.

Federal Food, Drug and Cosmetic Act.

"*Section 201.* Definitions; generally. [21 U. S. C. 321.]

"For the purposes of this chapter—

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."

"*Section 301.* Prohibited acts. [21 U. S. C. 331.]

"The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

"*Section 303.* Penalties—Violation of Sec. 301. [21 U. S. C. 333.]

(a) Any person who violates any of the provisions of Section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to

imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine * * *."

"*Section 501.* Adulterated drugs and devices. [21 U. S. C. 351.]

"A drug or device shall be deemed to be adulterated—

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess."

"*Section 502.* Misbranded Drugs and devices. [21 U. S. C. 352.]

"A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular."

IV.

QUESTIONS INVOLVED.

It appears from the contentions in Appellants' brief that the following questions are presented by this appeal:

(1) Is there substantial evidence to support the District Court's conclusion that the products involved were adulterated or misbranded when the appellants introduced them into interstate commerce?

(2) Was there prejudicial error in the hypothetical questions which the Government's witnesses were permitted to answer?

V.
SUMMARY OF ARGUMENT.

A. The District Court's Judgments of Conviction Are Supported by Substantial Evidence.

The Government's burden was to prove its case beyond a reasonable doubt, not beyond all doubt.

The products involved in this case were very stable in themselves and were packaged, corked and sealed in a manner best designed to preserve such integrity as they had when they were manufactured.

Appellants shipped these products to doctors in the regular course of business. Government inspectors obtained a portion of each of these shipments from the doctors and sent them in the regular course of business to Food and Drug Administration laboratories in Washington, D. C. Upon receipt by the Government's chemists the products were full, sealed and apparently untampered with.

Only such highly unusual and improbable circumstances as boiling for five or six hours, or freezing, or adding additional ingredients could have affected the contents of the products.

The Government does not have to exclude all possibility that the products may have been tampered with. Whether these products actually were tampered with or substantially changed *after* their interstate shipment was a question of fact for the court sitting without a jury.

The products were therefore in substantially the same condition when received and analyzed by the chemists as they had been when appellants shipped them interstate, a relatively short time before.

Appellants admit that the "Indoform" (Counts I and II) contained practically no posterior pituitary, though the label declares the presence of 3 units per cc. The Government's chemist affirmatively established that either there was no posterior pituitary present or it was present in such small amounts as to be immeasurable.

The thyroid substance which the "Indoform" label declared to be present in the product signifies the *active constituent* of the thyroid, which is organically combined iodine [R. 89]. No organically combined iodine was found in the product, on analysis.

Appellants admitted there was no iodine present but contended that doctors were informed of this fact by the label disclaimer—"This preparation does not contain any known therapeutically useful constituent." This label is misleading (1) because other constituents in the product admittedly *do have* therapeutic value, and (2) there is no clear-cut statement that this particular thyroid substance does not contain the iodine constituent.

Uncontradicted evidence as to the product "Pluri-B" (Counts III and IV) established that it contained only 33 milligrams of thiamine hydrochloride per cc., though the label declares the presence of 50 milligrams. Defendants admitted that at the time they shipped this product

they did not have the equipment necessary to test the product and actually did not test it [R. 141, 144].

Manufacturers of drugs have a serious responsibility to the public to maintain controls necessary to secure the purity, potency and safety of their products.

Uncontradicted evidence as to the other shipment of "Pluri-B" (Count VII), established that it was badly contaminated with undissolved material visible to the naked eye. Such material is a menace to health in a product that is offered as a sterile solution for intramuscular or intravenous use.

B. No Error Was Committed by the District Court in Permitting The Government's Witnesses to Answer Hypothetical Questions.

In a criminal case which is tried by the court without a jury, it is assumed that the trial court considered only competent and material evidence. In such a case, the reception of incompetent evidence is not prejudicial.

However, even if there had been a jury trial, the questions were proper.

First, the evidence directly, fairly and reasonably tended to establish all of the facts assumed in each hypothetical question.

Second, the Government's experts gave their opinions not on any *ultimate* issues of fact but only with respect to those subsidiary issues of fact where their opinions were a proper aid to the court sitting without a jury.

VI.
ARGUMENT.

A. The Government's Burden Was to Prove the Defendants Guilty Beyond a Reasonable Doubt, But Not Beyond All Doubt; the District Court's Judgments of Conviction Are Supported by Substantial Evidence.

This is a criminal prosecution that was tried by the District Court, defendants having waived jury trial [R. 17]. We do not challenge appellants' assertion that it was incumbent upon the Government to prove its case "beyond a reasonable doubt." However, as appellants interpret this phrase, it means "beyond all doubt."

Such an argument was effectively laid to rest in *Henderson v. United States,* 143 F. (2d) 681 (C. C. A. 9th), where this court stated on page 682:

> "The proof in a criminal case need not exclude all doubt. If that were the rule, crime would be punished only by the criminal's own conscience, and organized society would be without defense against the conscienceless criminal and against the weak, the cowardly, and the lazy who would seek to live on their wits. The proof need go no further than reach that degree of probability where the general experience of men suggests that it has passed the mark of reasonable doubt.
>
> "And judges and juries do not begin the solution of the complex problems presented to them from a zero of knowledge. They start with the vast common knowledge and understanding possessed by the people."

At another point, on page 682, the court said:

> "It is a familiar principle, which it is our duty to apply, that an appellate court will indulge all reasonable presumptions in support of the rulings of a trial court and therefore that it will draw all inferences permissible from the record, and in determining whether evidence is sufficient to sustain a conviction, will consider the evidence most favorably to the prosecution."

1. Identity of the Samples.

Appellants vigorously argue the proposition that the burden is upon the Government to establish that in reasonable probability the testimony of the Government's witnesses with respect to the condition of the products involved, *as of the date of analysis*, substantially reflects the condition of those products *as of the date defendants shipped them interstate*. With this proposition we have no quarrel.

Appellants quote from 32 *Corpus Juris Secundum*, Section 607, page 458 (App. Br. 23). One of the sentences omitted from this quotation reads:

> "It is unnecessary to show an absence of tampering on the part of every person through whose hands the article has passed; as long as the article can be identified it is immaterial in how many or in whose hands it has been."

Similarly, appellants quote from *United States v. S. B. Penick & Co.*, 136 F. (2d) 413, 415 (C. C. A. 2nd), (App. Br. 21). From this quotation, also, several sentences are omitted which we supply:

> "But there is no hard and fast rule that the prosecution must exclude all possibility that the article

may have been tampered with. See *Lestico v. Kuehner,* 204 Minn. 125, 283 N. W. 122, 125.

"Here the samples were taken in the ordinary course of business for the very purpose of being retained as samples; they were put in the usual place where samples were kept to remove them from accident or meddling and there they remained, so far as appears, undisturbed. We think this showing was sufficient to justify admission in evidence of the bottles and their contents and that it was for the jury to decide how likely it was that some other substance had been substituted for that which was originally put in the bottles. *Pennsylvania R. Co. v. Fox & London,* 93 F. (2d) 669 (C. C. A. 2nd), cert. den. 304 U. S. 566; *Hanify Co. v. Westberg,* 16 F. (2d) 552 (C. C. A. 9th)." (Emphasis supplied.)

In the instant case the Government undertook to establish the identity of the samples *as of the time of shipment,* by circumstantial evidence relating to their interstate shipment, the identity of the consignees and the condition of the drugs when received by the Government chemists, together with the reasonable inferences flowing from such evidence. The Government's evidence was strengthened by admissions in appellant Bavouset's testimony, which established (1) that the product "Indoform" was adulterated and misbranded when it was introduced into interstate commerce [R. 143], and (2) that all of the products here involved were likely to have been adulterated and misbranded at that time by reason of the poor manufacturing controls maintained by the appellants [R. 141-144].

Counts I, II, III, IV and VII involve the interstate shipment of three different products consigned to three different doctors. In each of these shipments there were

a number of vials.[1] The inference is clear that these shipments were made by the defendants in the regular course of business and so received by the doctors. Defendants clearly expected these products to maintain for a long period of time, whatever stability and integrity they had at the time of shipment. It is hardly conceivable that within a period of a few months, three of their products shipped to different doctors would have been subjected to freezing temperatures, boiling for five or six hours, and the addition of extraneous material.

The products bore no label statements suggesting special conditions of storage. It may reasonably be assumed that the doctors who received such products handled and stored them in the normal way.

Samples consisting of *a portion* of each of these shipments were obtained from the doctor consignees by inspectors of the U. S. Food and Drug Administration. The inspectors shipped the samples to the appropriate laboratories for analysis. Their testimony was deemed unnecessary in view of the stipulation entered into to shorten the trial. From the stipulation it is clear that the work done by the inspectors in connection with the collection and shipment of these samples was done in the ragular course of business and in the performance of their official duties. It may be presumed that such official duties were regularly performed. In *United States v. Chemical Foundation, Inc.*, 272 U. S. 1, at pages 14-15, the Supreme Court stated:

> "The presumption of regularity supports the official acts of public officers and, in the absence of clear

---

[1]It may be noted that the shipment described in Counts V and VI, with respect to which defendants were found not guilty, consisted of only *one vial* [R. 15-16].

evidence to the contrary, courts presume that they have properly discharged their official duties."

See, also:

Bowles v. Glick Bros. Lumber Co., 146 F. (2d) 566, at p. 571 (C. C. A. 9th);

Dunn v. Ickes, 115 F. (2d) 36-37 (C. A., D. C.), cert. den. 311 U. S. 698;

Calif. Code of Civ. Proc., Section 1963, Subd. (15).

It was testified by the chemists who analyzed these samples that, on receipt, each of the vials comprising the samples was full, sealed and apparently untampered with. The vials of amber colored glass were capped, sealed and packaged in accordance with the best known methods designed to protect the intergrity of the contents. Moreover, it was indisputably established that these products are extremely stable except under such unusual circumstances as boiling for five or six hours, freezing temperatures, addition of extraneous materials to contents, etc. Record references to these facts are fully set forth under the Government's "Statement of the Facts."

When it is considered that the vials in each sample were full, sealed with the manufacturer's seal—with contents apparently untouched when received by the analysts—there stands out in bold relief the futility as well as the staggering burden and expense of summoning officials and employees of the Railway Express Agency, the Post Office Department and the doctors, as well as any other persons who might have had anything to do with these products in the normal course of their interstate shipment. And for what purpose would such witnesses be called? To testify that they did not boil the products for six

hours—that they did not add other ingredients to the products though the products were sealed, capped and full, etc.! As a practical matter most persons who handled the transportation of these products in the regular course of business would have no recollection whatsoever about them, even if it were possible to locate them.

While defendants' witness, Dr. Icke, described fanciful conditions under which these products may have deteriorated subsequent to their interstate shipment, his credibility and the weight to be given his testimony were matters for the trial court, sitting without a jury.

Newman v. United States, 156 F. (2d) 8 (C. C. A. 9th), cert den.;

Cain v. United States, 67 S. Ct. 115.

A significant factor bearing upon the identity of the samples is the comparatively short time that elapsed between their interstate shipment by the defendants and their analysis by Government chemists. The "Pluri-B" involved in Count VII was shipped interstate on June 18, 1946, and was analyzed on August 1, 1946, less than six weeks later. The "Pluri-B" involved in Counts III and IV was shipped interstate on July 16, 1945, and analyzed on September 24, 1945, two months and one week later. The "Indoform" involved in Counts I and II was shipped interstate on September 17, 1945, and analyzed on February 18, 1946, five months later; defendants' admissions with respect to the "Indoform" make the five months lapse of time entirely immaterial, as will be shown shortly.

Also, the stipulation [R. 13-17] establishes that the doctors could have had the shipments in their possession only a short time before the samples were collected by the inspectors.

For these reasons we submit that the Government established beyond a reasonable doubt, if not beyond all doubt, that the samples concerning which the Government's witnesses testified were substantially the same on the date when their analyses were made, as they were at the time when defendants shipped them interstate.

2. Admissions by Defendants and Independent Proof of Violations.

With respect to the interstate shipment of "Indoform" (Counts I and II), defendant Bavouset, general manager of defendant Pasadena Research Laboratories, admitted that he had had this product independently tested by the Cooper Laboratories, who found it contained such small quantities of posterior pituitary as to be immeasurable [R. 143]. Defendants manufactured between 65 and 100 vials of "Indoform" at a time [R. 133]. The analysis by Cooper Laboratories was made *after* defendants had made the interstate shipment to Dr. Bunten [R. 14, 144]. This is one indication of the laxity of controls maintained by the defendants with respect to a drug to be administered by injection.

At any rate, the admission that the "Indoform" contained such small amounts of posterior pituitary as to be immeasurable is, in itself, enough to sustain the conviction on Counts I and II, since the label declares the presence of 3 units of posterior pituitary per cc. [R. 63]. The testimony of chemist Mason affirmatively and graphically establishes that there was no posterior pituitary present in the "Indoform," or if there was any there at all it was in such small amounts as to be immeasurable [R. 57-84, 215-226]. Posterior pituitary is very stable unless it is

kept at a boiling temperature for five or six hours [R. 73-74].

A second and independent reason for sustaining the conviction as to Counts I and II, is the further admission by defendant Bavouset that the "thyroid substance" which the label declared to be present in the "Indoform" was present in a form from which the potent organically-combined iodine had been removed [R. 110].

The definition of "thyroid" in the United States Pharmacopoeia states that it "contains not less than 0.17 per cent and no more than 0.23 per cent of iodine in thyroid combination" [R. 136-137]. Government witness Buell testified that the label statement, "each cc. contains Thyroid Substance I grain," means one grain of the active constituent of the thyroid as organically-combined iodine [R. 89]. Mr. Buell analyzed the product and found no thyroid present at all [R. 89]. The iodine in thyroid is extremely stable [R. 89-90].

A colloquy between the court and defendant Bavouset indicates the nebulous and shifty character of defendants' operations [R. 111-112]:

> "The Court: Then this Indoform did not purport to contain any iodine?
>
> The Witness: No, sir.
>
> The Court: What is the thyroid substance here it did purport to contain?
>
> The Witness: Your Honor, I do not know the type of material that is designated therein. We put a disclaimer on the product, stating that it did not contain therapeutically useful constituents to let the doctor know that the thyroid content was not the iodine content.

The Court: In the trade would the term 'thyroid substance' have any particular meaning?

The Witness: In the trade the words 'thyroid substance' for oral administration would mean the whole gland, that is, of course, meant to feed it or made ready for oral administration.

The Court: And that would contain iodine?

The Witness: Yes, your Honor; that would contain iodine.

Q. By Mr. Stick: In an aqueous solution would it contain that? A. No, it would not.

The Court: Is there anything on the label, this Indoform label, to indicate it is an aqueous solution?

The Witness: I do not believe so, your Honor * * *."

The so-called disclaimer which Mr. Bavouset thought would inform the doctor "that the thyroid content was not the iodine content," reads as follows:

"This preparation does not contain any known therapeutically useful constituent." [R. 63.]

The misleading nature of this disclaimer becomes clearer in the light of Mr. Bavouset's further admission that other constituents of "Indoform" such as posterior pituitary and whole ovarian *do have therapeutic value* [R. 135].

Appellants did not unequivocally state on the label that the "thyroid substance" did not contain any of the iodine constituents which are normally in the thyroid, though he, Bavouset, protests that that was his intention [R. 135]. Actually, the statement of ingredients on the label declares that each cc. contains 1 grain of thyroid substance. This statement is false and misleading as charged

in Count II. In *United States v. 95 Barrels * * * Vinegar,* 265 U. S. 438, the court observed on pages 442-443:

> "The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act."

Section 201(n) of the Act [21 U. S. C. 321(n)] sets forth statutory criteria useful in striking at half truths in products whose labeling is charged with being misleading. That section reads in part:

> "* * * in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made * * * *but also the extent to which the labeling fails to reveal facts material in the light of such representations* * * *."

When a product is represented as containing thyroid substance, the only active constituent of which is its iodine content, we submit that the labeling of the product is misleading when it fails to reveal in definite terms *the material fact* that this particular thyroid substance does not contain the iodine constituent.

An analogous situation arose in *H. N. Heusner & Son v. Federal Trade Commission,* 106 F. (2d) 596 (C. C. A. 3rd). That was a petition to modify an order issued by the Federal Trade Commission to cease and desist from using the word "Havana" on cigars which petitioner manufactured in Pennsylvania, from Pennsylvania tobacco, and which he branded "Havana Smokers." Petitioner sought retention of the word "Havana" to be used with this legend: "Notice. These cigars are made in the United States, and only of United States tobacco." On page 597, the court rejected this argument in terms that are quite appropriate here:

> "The difficulty of petitioner's position lies in the fact that the implication of the word 'Havana' is totally false. The purchaser can be guided by either label or legend, but not by both * * *. We doubt if petitioner would accede to a true qualification—'Fake Havana Smokers.'"

With respect to the interstate shipment of "Pluri-B" (Counts III and IV), the uncontradicted evidence is that the sample analyzed by Government witness Capps [Govt. Exhibit 6] contained only 33 milligrams of thiamine hydrochloride per cc. [R. 100], though the label declares the presence of 50 milligrams of thiamine hydrochloride per cc. [R. 107].

When thiamine hydrochloride is put in a properly made solution, it is a stable product unless exposed to extremely high temperatures [R. 100]. Defendant Bavouset testified that the solution of this "Pluri-B" was very acid, which he stated is a proper base for retention of the potency of the product [R. 151]. He informed the court he would not expect the product to have lost its potency even a year after it was made [R. 149]. The label of

the product specifies no particular conditions of storage [R. 107].

Coupled with this affirmative evidence there is the admission by defendant Bavouset that at the time when this shipment was made, the defendants *did not have the equipment necessary to make the thiocrome determination for thiamine* [R. 144], which is prescribed by the United States Pharmacopoeia [R. 199-200]. Defendants in fact did not have assays conducted on any of the finished products here involved with the exception of "Indoform," "because the facilities were not available at that time" [R. 141]; and that one assay, which was made *after* interstate shipment, itself established a violation [R. 143].

We feel, and the courts have recognized, that manufacturers of drugs have a serious responsibility to the public to maintain controls designed to secure the purity, potency and safety of their products. In *United States v. Dotterweich,* 320 U. S. 277, the Supreme Court declared with respect to the Federal Food, Drug and Cosmetic Act:

> *Page 280.*
>
> "The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."
>
> *Page 281.*
>
> "Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it

puts the burden of acting at hazard upon a person otherwise innocent but standing in a responsible relation to a public danger."

Pages 284-285.

"Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."

See, also, *United States v. Parfait Powder Puff Co.,* 163 F. (2d) 1008 (C. C. A. 7th), cert. den. 92 L. Ed. 318. In such matters the public, including doctors, are helpless because they are not in a position to make tests and assays upon the innumerable products flowing through commerce. A major purpose of the Federal Food, Drug and Cosmetic Act is to protect the public health by pinning responsibility upon those who are in the logical position to assume it—*e. g.,* the manufacturers and distributors.

With respect to the other shipment of "Pluri-B" (Count VII), the uncontradicted evidence is that all the vials in the sample examined by Government witness Wiley [Govt's Exhibit 1] were badly contaminated with undissolved material visible to the naked eye [R. 34]. The label declares that this product is a sterile solution for intramuscular or intravenous use [R. 35].

The standards of the United States Pharmacopoeia for such a product call for its being free from undis-

solved material [R. 50]. Dr. Thienes testified to the harm that could result from injecting such a solution containing undissolved material, intravenously or intramuscularly [R. 49-50].

The presence of the undissolved material was caused by the fact that the product contained more riboflavin than could be dissolved in that amount of fluid; the solution was supersaturated [R. 44]. After examining the vials comprising Government's Exhibit 1, appellant Bavouset stated that nothing had been added to them other than what he had put into them [R. 146].

Appellants' witness, Dr. Icke, stated that by exercising careful simple controls, a manufacturer could be certain to detect the presence of supersaturated solutions of riboflavin [R. 192]. He also testified that in his opinion, the undissolved particles in Government's Exhibit 1 would dissolve if the vials were placed in warm or lukewarm water [R. 190].

Government's witness, Dr. Wiley, stated in rebuttal that as a matter of routine laboratory procedure, he placed these vials in warm water of about 150° Fahrenheit and kept them there for ten to fifteen minutes, at the end of which time the undissolved material was still there [R. 226-227].

The court, in comparing the "Pluri-B" involved in Counts III and IV, with the "Pluri-B" involved in Count VII, noted that the label of the first declared the presence of only one milligram of riboflavin per cc. [R. 107], while

the label of the second declared the presence of two milligrams of riboflavin per cc. [R. 35]. In questioning defendant Bavouset about these two products the court brought out the testimony that the "Pluri-B" with one milligram of riboflavin per cc. is just as efficacious as the "Pluri-B" with two [R. 149]. Also, since there is danger of precipitation of riboflavin, it would be a safer product with less riboflavin in it [R. 149].

The following is taken from page 147 of the Record:

> "The Court: Is there some definite purpose in including in one of the Pluri-B products only one milligram of riboflavin per cubic centimeter and, in the other, two milligrams?
>
> The Witness: Yes, your Honor. The intramuscular, as I said, it was quite stable and we had a lot of success with it. And then we put in two milligrams. *Perhaps I was a little optimistic,* I don't know, and we had a great deal of good fortune with that at all times, and *upon a very rare occasion something like this did happen.*" (Emphasis supplied.)

The District Court could well question this blithe optimism with respect to a product that could be dangerous to persons in whom it might be injected.

We submit that there was clearly substantial evidence to support the District Court's finding that each of the products involved in this appeal was adulterated and misbranded as charged in the Information.

B. No Error Was Committed by the District Court In Permitting the Government's Witnesses to Answer Hypothetical Questions.

In our understanding of the law, Appellants' entire argument with respect to hypothetical questions is immaterial since this case was tried without a jury [R. 17].

The rule is well established that in a criminal case which is tried by the court without a jury, it is assumed that the trial court considered only competent and material evidence; consequently, the reception of incompetent evidence is not prejudicial. In *Hoffman v. United States,* 87 F. (2d) 410 (C. C. A. 9th), this court stated at page 411:

> "This case was tried by the judge and presumably he would consider only material and competent testimony."

And in *Gates v. United States,* 122 F. (2d) 571 (C. C. A. 10th), cert. den. 314 U. S. 698, the court said on page 578, citing the *Hoffman* case and others:

> "Where a case is tried to the court without a jury, it is assumed that the court considered only competent and material evidence, and disregarded incompetent, immaterial and improper evidence."

See also:

Daniel v. United States, 127 F. (2d) 1 (C. C. A. 8th), cert. den. 317 U. S. 641;

United States v. David, 107 F. (2d) 519 (C. C. A. 7th).

We do not concede, however, that the questions asked would have been improper in any respect even if there had been a jury trial.

First, we submit that the evidence directly, fairly and reasonably tended to establish all of the facts assumed in each hypothetical question within the requirements laid down by this court in *Travelers Ins. Co. v. Drake,* 89 F. (2d) 47, 50 (C. C. A. 9th). Essentially, our argument on this point would be the same as that already made in Part "A," subdivision "1" of this argument, namely, that the shipments were all made in the regular course of business and it could reasonably be inferred from the evidence that none of the persons in any way connected with the products had boiled them, frozen them or added other ingredients to them. Any other inference would be unreasonable in view of the intact condition of the products when received by the analysts, and in view of the common understanding of conditions that prevail (1) in the regular course of interstate shipment, (2) in the offices of doctors who purchase products for use in treating their patients, and (3) in the collection and handling of official samples taken pursuant to the Federal Food, Drug and Cosmetic Act.

Second, we believe that Appellants' Brief (p. 33) does not correctly state the law with respect to the scope of hypothetical questions that may properly be propounded to expert witnesses.

It is fundamental that the scope and fairness of a hypothetical question are matters resting largely in the discretion of the trial court.

> *United States v. Aspinwall,* 96 F. (2d) 867, 869 (C. C. A. 9th).

See also—

Moyer v. Aetna Life Ins. Co., 126 F. (2d) 141, 144 (C. C. A. 3rd).

Even—

"* * * where a witness answers a hypothetical question not founded on all the facts of the case, the defect goes not to the competency of the evidence but merely affects its weight."

Permanente Metals Corp. v. Pista, 154 F. (2d) 568, 569 (C. C. A. 9th).

See also—

Forsyth v. Doolittle, 120 U. S. 73, 74;

United States v. Johnson, 319 U. S. 503, 519.

We submit that these cases support the proposition that the interrogating counsel may properly assume any state of facts reasonably supported by the evidence, and may limit those facts within limits permitted in the discretion of the trial court.

Appellants cite *United States v. Spaulding,* 293 U. S. 498 (App. Br. 33), and other cases involving war risk insurance policies in support of the proposition that experts may not state their opinions with respect to the ultimate issues of fact. In the *Spaulding* case, the ultimate issue of fact was whether the respondent was suffering from "total permanent disability," *as those words are used in the policy and statute authorizing the insurance.* The court said (p. 506):

"* * * that question is not to be resolved by opinion evidence. It was the ultimate issue to be decided by the jury upon all the evidence in obedience to the judge's instructions as to the meaning of the crucial phrase and other questions of law."

Similar rulings were made in the other cases cited by appellants, namely, that the experts could not testify that the insurance claimants were *totally and permanently disabled.*

These rulings, we submit, have no bearing on the instant case since none of the questions asked of the experts elicited opinions with respect to the ultimate issues of fact. What are the ultimate issues in this case? They are found in the Information, which reflects the statutory language —were these products *adulterated* or *misbranded* when defendants introduced them into interstate commerce? These issues may be further broken down in the statutory language as follows:

(1) Was the "Indoform" adulterated in that its strength differed from that which it purported or was represented to possess? (Count I).

(2) Was the "Indoform" misbranded in that the statements displayed on the vials of said drug were false or misleading? (Count II).

(3) Was the "Pluri-B" adulterated in that its strength differed from that which it purported or was represented to possess? (Count III).

(4) Was the "Pluri-B" misbranded in that a statement displayed on the vials of said drug was false or misleading? (Count IV).

(5) Was the "Pluri-B" adulterated in that its purity or quality fell below that which it purported or was represented to possess? (Count VII).

The Record shows that no expert witness called by the Government gave an opinion with respect to any of these ultimate issues of fact. Nor do the hypothetical questions

which appellants are attacking (App. Br. 26), include any attempt to elicit an opinion as to such ultimate issues. No expert witness testified that in his opinion a product here involved was adulterated when it was introduced into interstate commerce, or that its purity and quality fell below that which it purported and was represented to possess. Instead, the witnesses testified, for example, that the undissolved material was undoubtedly present on June 18, 1946, when it was shipped [R. 41-42].

Of course, the testimony of the Government's experts was related to the issues of fact; otherwise it would have been immaterial. But the opinions they gave were not determinative of the ultimate issues. Thus they in no way infringed upon the function of the trier of the facts to decide whether the "Indoform" was "adulterated when introduced into interstate commerce, in that its strength differed from that which it purported or was represented to possess." The meaning of this statutory language was not interpreted by the experts or applied by them to the facts of the case. Whether undissolved material was present at a certain date was a subsidiary issue of fact, concerning which a qualified expert could properly express an opinion.

In *Transportation Line v. Hope,* 95 U. S. 297, the court said on page 298:

> "It is not an objection * * * that he was asked a question involving the point to be decided by the jury. As an expert he could properly aid the jury by such evidence."

And in *Travelers Ins. Co. v. Drake,* 89 F. (2d) 47 (C. C. A. 9th), this court upheld the admission of a doctor's evidence on the cause of a death, observing on page 49:

> "While the jury is the sole judge of the facts as to the issue of death and cause of death, that does not, however, make objectionable the opinion of a medical expert in aid to the jury to find the ultimate fact."

See, also—

Cropper v. Titanium Pigment Co., 47 F. (2d) 1038 (C. C. A. 8th), 78 A. L. R. 737, 755;

Francis v. Southern Pac. Co., 162 F. (2d) 813, 817 (C. C. A. 10th);

United States Smelting Co. v. Parry, 166 Fed. 407, 410-415 (C. C. A. 8th).

In litigation under the Federal Food, Drug and Cosmetic Act, the propriety of eliciting expert opinions with respect to such factual issues as the therapeutic efficacy of a drug in the treatment of the ailments for which it is offered, is frequently challenged. Invariably such objections are overruled.

Kar-Ru Chemical Co. v. United States, 264 Fed. 921, 928 (C. C. A. 9th);

*Eleven Gross Packages * * * Dr. Williams' Pink Pills v. United States,* 233 Fed. 71, 73 (C. C. A. 3rd);

United States v. One Device, intended for use as a Colonic Irrigator, 160 F. (2d) 194, 199 (C. C. A. 10th).

One sentence in *United States v. 7 Jugs * * * Dr. Salbury's Rakes,* 53 Fed. Supp. 746 (D. Minn.), sums up the rationale for these rulings:

Page 760.

"All of the opinion evidence given by the Government's experts necessarily involved the use of their experience and training on matters of special knowledge not within the grasp of the untutored."

C. Miscellaneous Points.

Appellants contend that certain statements made by Government witness Mason are contradictory and that he was biased (App. Br. 19). Such assertions are not borne out by the Record.

Mr. Mason, who at the time of his testimony was no longer employed with the Food and Drug Administration [R. 57], was particularly meticulous in describing precisely what he had done in the course of his analysis of appellants' product "Indoform," and what he had observed with respect to it [R. 57-84, 215-225].

The following is quoted from the Record, pages 78-80, with respect to the "Indoform," Exhibit 3 (the witness being Mr. Mason):

"The Court: Was that cork sealed *into* the bottle in any way?

The Witness: I do not remember whether it was sealed *into* the bottle or not. It has the same type of rubber stopper that is commonly on such preparations.

* * * * * * * *

The Court: Was the bottle, Exhibit 3, at the time you received it corked or closed and sealed in the same manner or a similar manner [as Exhibit 1]?

The Witness: It was sealed in the same manner as Exhibit No. 1.

Q. * * * * * * * *

A. The rubber cork goes down into the neck of the bottle for a short distance, folds around the outside of the bottle, then is sealed with a plastic seal.

* * * * * * * *

The Court: Did this Exhibit 3, when you received it, the bottle, appear to be so corked?

The Witness: Yes, sir.

The Court: As counsel has just described it?

The Witness: Yes, sir.

The Court: That is, corked and sealed?

The Witness: Corked and sealed.

* * * * * * * *

The Court: Now did this bottle, Exhibit 3, at the time you first saw it appear to be corked and sealed in the same manner as defendants' 'A' for identification?

The Witness: In the same or similar manner."

It is quite clear, from this series of questions and answers, that Mr. Mason testified the product he received was corked and sealed with a plastic seal. It is not certain just what the court meant in the first question quoted above, when it asked whether the cork was sealed *into* the bottle. The witness didn't know whether it was sealed *into* the bottle, but he did know that the bottle was sealed on the *outside*. Consequently, when he testified on rebuttal that "the vial was full and the rubber stopper or cork was protected with a celluloid seal around it when I received it; it appeared as if it had never been opened" [R. 215]—he was merely clarifying statements he had already made. The Record, we submit, does not justify the distorted conclusions drawn by appellants.

VII.
CONCLUSION.

The convictions as adjudged by the court were supported by clear and substantial evidence, enhanced by appellants' admissions as to laxity in the maintenance of manufacturing controls.

We submit that the judgments of the District Court should in all respects be affirmed.

Respectfully submitted,

James M. Carter,
United States Attorney,

Ernest A. Tolin,
Chief Assistant U. S. Attorney,

Norman W. Neukom,
Assistant U. S. Attorney,
Chief of Criminal Division,

Attorneys for Appellee.

Arthur A. Dickerman,
Of Counsel—Attorney, Federal Security Agency.